CLIA RESOURCE CENTER
CLINICAL PATHOLOGY DEPARTMENT
NATIONAL INSTITUTES OF HEALTH
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BETHESDA, MD 20892

CLIA CHECKLIST

Quality Assurance

-- Lab director or designee reviews all results
-- Inconsistent results are investigated and resolved with documentation in writing
-- Testing personnel are documented on an annual basis to be competent in all tasks performed
-- Review QC data record lot #'s expiration dates, open dates
-- Review PT data and document
-- Keep discontinued procedure for 2 yrs.
-- Communicate changes to staff (staff meetings)
-- Validation of in house tests-precision/accuracy: sensitivity/specificity
-- Corrected reports-contact requester with corrected report alert limits report
-- Review results for relevance to patient data (i.e. age, sex, and other pertinent clinical data)
-- Action taken if discrepancy is discovered, monitor complaints received from users
-- QA records are maintained for at least two years
-- Keep discontinued procedures for two years

Quality Control

-- Laboratory had appropriate environmental conditions (i.e. lab has defined condition in which testing may be performed, temperature, humidity, etc.)
-- Procedure manuals

All tests procedures are written and complete including
- -- Test name
- -- Principal of the test
- -- Necessary equipment
- -- Directions for specimen collection and handling
- -- Directions for calibration or standardization
- -- Directions for preparation of reagents, standards and controls
- -- Step-by-step directions for performing the test
- -- Quality control procedures and criteria defining unacceptable control results
- -- Corrective actions when control criteria are exceeded
- -- Reference ranges
- -- Directions for calculation of results where appropriate
- -- Notes, safety procedures
- -- References

-- New procedures are reviewed and signed by director
-- Procedures are reviewed by the lab director or designee annually
-- All tests must be validated prior to reporting patient results. Precision, accuracy,

sensitivity, and specificity of the test must be established.
-- Reference ranges (if pertinent) must be established and reported with the results
-- A written QC policy includes:

    -- Frequency of performing controls for each test/record lot #'s and date
    -- At least two levels of control samples must be tested once a day of operation with each run (i.e. high /low or positive/negative)
    -- The type of control
    -- Acceptable limits for the control results
    -- Results not reported if out of control
-- Corrective actions taken when results have exceeded acceptable limits have been reviewed
-- A policy to assure abiding by QC criteria is established
-- Instrumentation
    -- Equipment is calibrated every 6 months and documentation is available for review
    -- Equipment is maintained according to manufacturer's recommendations
    -- Maintenance documents are reviewed
    -- Temperature dependent instruments are checked and recorded each day of use
    -- Acceptable ranges are defined for all temperature dependent equipment
    -- Minimum /mid point/ maximum values required to verify range
    -- Comparison of results of same specimen ran on two instruments of the same model, make, etc.
-- Reagents, dated, expiration date, etc. when open
-- Keep records two yrs.

Patient Test Management

-- Written policies and procedures are available for specimen collection, labeling, and preservation and handling including collection container, vol., transport criteria, labeling (safeguards for same first, last name)
-- Written criteria are available for rejection of unacceptable specimens
-- Test requisition includes:
    -- Name of patient with identifier
    -- Name and address of individual ordering test
    -- Test to be performed
    -- Date (time if critical) of specimen collection
    -- Any additional information relevant and necessary to assure accurate and timely testing
    -- Oral requests must have written follow up within 30 days
-- Experimental data
    -- Test name
    -- Patient name or unique ID
    -- Date received and/or tested
    -- Test results
    -- Indicate if unacceptable specimen
    -- QC results and acceptable ranges
    -- Indicate that QC results are acceptable

    -- Indicate who performed test
    -- Instrument printout of patient test results
-- Test reports to physicians and or patients
    -- Lab name and address of laboratory performing test
    -- Patient name or unique ID
    -- Test name
    -- Test results
    -- Normal ranges
    -- Indicate if unacceptable specimen (i.e. condition and disposition of specimen)
    -- Date of report
    -- Special interpretation notes explanation
    -- Disclaimer
      "This test was developed and its performance characteristics determined by (insert name of lab). It has not been cleared or approved by the U.S. Food and Drug Administration.
-- Test results secured confidential
-- Easily retrieved
-- If specimen is not tested--report includes disposition of specimen (repeat specimen requested)
-- If incomplete information is received steps to be taken -documents attempts to receive needed information, and attempts to prevent reoccurrence
-- Lab maintains record of reports for 2 years on a manner that can be readily retrieved
-- Lab maintains record of information contributing to test result for 2 years on a manner that can be readily retrieved
-- Referral of specimens for testing to a laboratory possessing a valid CLIA certificate
-- Expected turn around time

Proficiency Testing
-- Testing is performed every six months using:
    -- Commercially available analyte
      -Or-
    -- Positive and negative samples from previous runs are performed every 6 months or high and low level sample for quantitative test
-- Samples are blinded to the tester
-- Results are held maintained and available for review for a minimum of 2 years
-- Established target values for PT material
-- Acceptable levels of variation are established and results meet acceptable or unacceptable criteria
-- Document corrective action- notify testing personnel to prevent reoccurrence
-- Review for effective corrective action- no repeat occurrence
-- Review of proficiency testing: initial of Director/date

Personnel Qualifications
-- Education and experience of all personnel are on file in the human resources department or a copy of highest degree may be found in the laboratory standard operating procedure manual

-- Personnel policies are available for review
-- Testing personnel have had competency documented once a year; new employees at six months and annually thereafter
-- Training of new personnel is documented

Safety
-- Universal precautions are followed
-- Training is documented annually
-- Radiation Safety (RSB)
-- Environmental monitors- room temp 65-75
-- If particular requirements -state acceptable limits and how they are monitored